FEB 15 2008

5.0 510(k) SUMMARY

In accordance with Title 21 Code of Federal Regulations (21 CFR), Part 807, and in particular, §807.92, the following 510(k) summary is provided for the *Extended VertiFlex® Spinal Screw System*:

5.1 Submitted By:

VertiFlex®, Incorporated
1351 Calle Avanzado
San Clemente, California 92673

Contact: Steve Reitzler, Vice President of Regulatory & Quality Assurance

Date Prepared: November 14, 2007

5.2 Device Name

Trade or Proprietary Name:	*Extended VertiFlex® Spinal Screw System*
Common or Usual Name:	Pedicle Screw System
Classification Name:	Pedicle Screw Spinal System
Classification Regulation:	21 CFR, §888.3070
Product Codes:	MNH, MNI, NKB

5.3 Predicate Devices

The subject device is substantially equivalent, in whole or in part, to the following commercially available predicate devices:

VertiFlex® Spinal Screw System (VertiFlex®, Inc., K062670)

5.4 Device Description

The *Extended VertiFlex® Spinal Screw System* is a posterior, non-cervical instrumentation system consisting of both pedicle screws and rigid connecting rods. Screws are of polyaxial or monoaxial (fixed) top-loading design, are composed of titanium alloy conforming to ASTM F136, and are available in a range of diameters and lengths to accommodate physiological requirements. The rods are composed of titanium conforming to ASTM F67, and are available in both straight and curved (pre-lordosed) styles, and in a range of lengths to accommodate both single-level and multiple levels procedures. The *System* may be implanted by either conventional surgical methods, or via minimally-invasive/percutaneous techniques, although the line extension which is a subject of this submission is designed specifically to facilitate MIS/percutaneous use. Manual instrumentation for implantation of the *System* is available for both conventional and minimally-invasive procedures. The modifications that are the subject of this submission consist of the addition of rod and screw components designed to more easily create multi-level constructs percutaneously, and screws having smaller diameters. Screws, rods, and instruments are offered non-sterile.

5.5 Intended Use

The subject device is indicated for use as follows:

When used as a posterior, noncervical pedicle screw system, the Extended VertiFlex® Spinal Screw System *is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar, and sacral spine:*

- *Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;*
- *Severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra;*
- *Degenerative spondylolisthesis;*
- *Trauma (i.e., fracture or dislocation);*
- *Spinal stenosis;*
- *Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);*
- *Tumor;*
- *Pseudoarthrosis; and/or*
- *Failed previous fusion.*

5.6 Comparison to Predicate Device

In accordance with the agency guideline entitled *The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications* (March 1998), VertiFlex® has established, through rigorous design control processes conforming to 21 CFR §820.30, and a comprehensive risk analysis. that the subject *Extended VertiFlex® Spinal Screw System* is substantially equivalent to the commercially-available predicate *VertiFlex® Spinal Screw System.* Further, the subject modifications (a) do not alter the intended use, (b) do not alter the fundamental technological principles of the device, and (c) continue to meet all design input requirements.

5.7 Summary of Non-Clinical Tests

Such verification and validation tests as were identified as appropriate to address the results of a risk analysis for the subject *Extended VertiFlex® Spinal Screw System* were completed, and all acceptance criteria were met.

5.8 Summary of Clinical Tests

No clinical testing was conducted to support this submission.

5.9 Conclusions

The results of all design, risk analysis, and verification and validation activities support the substantial equivalence of the subject *Extended VertiFlex® Spinal Screw System* to the predicate *VertiFlex® Spinal Screw System*, and establish that the subject device continues to meet all design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2008

Vertiflex, Inc.
% Mr. Steve Reitzler
1351 Calle Avanzada
San Clamente, CA 92673

Re: K073245
Trade/Device Name: Extended Vertiflex Spinal Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, MNH
Dated: January 14, 2008
Received: January 16, 2008

Dear Mr. Reitzler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073245

Device Name: *Extended VertiFlex® Spinal Screw System*

Indications for Use:

When used as a posterior, noncervical pedicle screw system, the *Extended VertiFlex® Spinal Screw System* is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies;
- Severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra;
- Degenerative spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and/or
- Failed previous fusion.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073245

Concurrence of CDRH, Office of Device Evaluation (ODE)